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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,633	09/29/2004	Jean-Claude Arnould	ASZD-P01-467	4294
44992	7590	12/13/2005	EXAMINER	
ASTRAZENECA R&D BOSTON 35 GATEHOUSE DRIVE WALTHAM, MA 02451-1215			GRAZIER, NYEEMAH	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/509,633	Applicant(s) ARNOULD, JEAN-CLAUDE	
	Examiner Nyeemah Grazier	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/30/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-12 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION
Lack of Unity of Invention

I. ACTION SUMMARY

Claims 1-12 are currently pending in the instant application.

II. PRIORITY

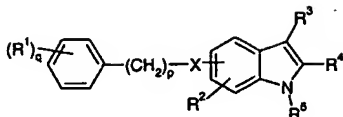
This application is a 371 of PCT/GB03/01405, filed on March 31, 2003. Applicant's claim for priority under 35 U.S.C. § 119(a-d) to foreign application EPO 02290822.2 filed on April 3, 2002 is hereby acknowledged.

III. RESTRICTION-LACK OF UNITY OF INVENTION

Restriction is required under 35 U.S.C. 121 and 372 because the instant application contains the following inventions or groups of inventions which are not so linked to form a single general inventive concept under PCT Rule 13.1. Therefore a restriction is required according to the provision of PCT Rule 13.2.

The instant application contains Markush practice. However, pursuant to Section B (Markush Practice) MPEP § 1850 (B), the invention does not meet the unity of invention criteria because (1) the core structure is not the unifying criteria and (2) the variables do not belong to a "recognized class of chemical compounds in the art to which the invention pertains." MPEP § 1850 (B) (2004).

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Formula (I),  , as recited in Claim 1 is the genus. The special

technical feature is the indole ring wherein the ring nitrogen of the heterocyclic ring is substituted by a benzyl group. Unity of invention is lacking because the core is not novel, *infra*. Claims 1-12 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2.

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention). PCT Rule 13.2 states unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1 (b), provides that “special technical features” mean those technical features, which, as a whole, define a contribution over the prior art.

Annex B, Part 1 (e), provides combinations of different categories of claims and states:

“The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

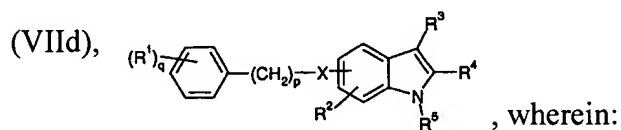
- (i) in addition to an independent claim for a given product, an independent claims for a process specially adapted for the manufacture of the said product, and an independent claim for use of the said product, or
- (ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specially designed for carrying out the said process, or
- (iii) in addition to an independent claim for a given product, and independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specially designed for carrying out the said process,...

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This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Due to the numerous and widely-divergent variables in the compound of Formula (IA), such as **R1, R2, R3, R4, R5, R6 X** etc. a precise listing of inventive groups cannot be made. *The following groups are exemplary:*

Group I: Claims 7-12, drawn to compounds, compositions and process of making formula



X is oxygen;

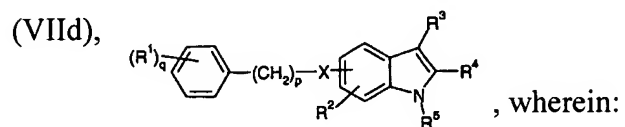
R¹ is $-\text{OPO}_3\text{H}_2-$;

R⁵ is selected from the group hydrogen, C₁-C₄ alkyl.

R², R³, R⁴, R⁶, R⁷ and R⁸ are defined in claim 1;

Y, Z, r, t, n, R⁹, R¹⁰, p, q are defined in claim 1.

Group II: Claims 7-12, drawn to compounds, compositions and process of making formula



X is S;

R¹ is $-\text{OPO}_3\text{H}_2-$;

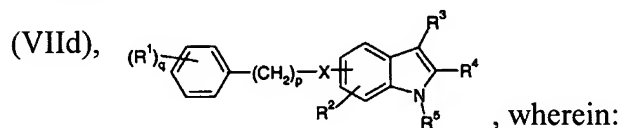
R⁵ is selected from the group hydrogen, C₁-C₄ alkyl.

R², R³, R⁴, R⁶, R⁷ and R⁸ are defined in claim 1;

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Y, Z, r, t, n, R⁹, R¹⁰, p, q are defined in claim 1.

Group III: Claims 7-12, drawn to compounds, compositions and process of making formula



X is SO or SO₂;

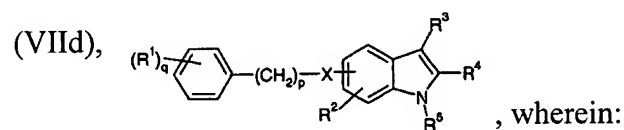
R¹ is -OPO₃H₂-;

R⁵ is selected from the group hydrogen, C₁-C₄ alkyl.

R², R³, R⁴, R⁶, R⁷ and R⁸ are defined in claim 1;

Y, Z, r, t, n, R⁹, R¹⁰, p, q are defined in claim 1.

Group IV: Claims 7-12, drawn to compounds, compositions and process of making formula



X is oxygen;

R¹ is independently selected from halo, hydroxyl, amino, alkanoylamino, or C1-

C4alkoxy, wherein the amino group is optionally substituted with an amino acid

residue and the hydroxyl group is optionally esterified;

R⁵ is selected from the group hydrogen, C₁-C₄ alkyl.

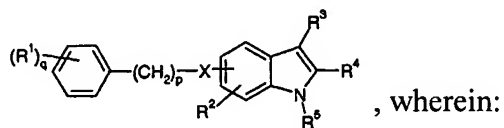
R², R³, R⁴, R⁶, R⁷ and R⁸ are defined in claim 1;

Y, Z, r, t, n, R⁹, R¹⁰, p, q are defined in claim 1.

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Group V: Claims 7-12, drawn to compounds, compositions and process of making formula

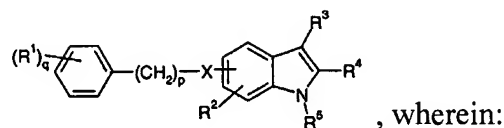
(VIId),

**X** is S;**R¹** is independently selected from halo, hydroxyl, amino, alkanoylamino, or C1-

C4alkoxy, wherein the amino group is optionally substituted with an amino acid residue and the hydroxyl group is optionally esterified;

R⁵ is selected from the group hydrogen, C₁-C₄ alkyl.**R², R³, R⁴, R⁶, R⁷ and R⁸** are defined in claim 1;**Y, Z, r, t, n, R⁹, R¹⁰, p, q** are defined in claim 1.**Group VI:** Claims 7-12, drawn to compounds, compositions and process of making formula

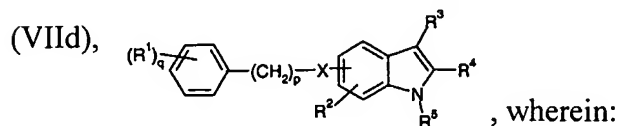
(VIId),

**X** is SO or SO₂;**R¹** is independently selected from halo, hydroxyl, amino, alkanoylamino, or C1-

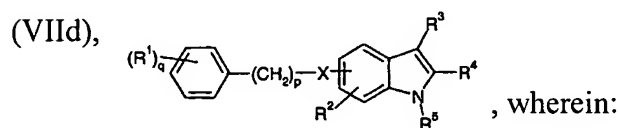
C4alkoxy, wherein the amino group is optionally substituted with an amino acid residue and the hydroxyl group is optionally esterified;

R⁵ is selected from the group hydrogen, C₁-C₄ alkyl.**R², R³, R⁴, R⁶, R⁷ and R⁸** are defined in claim 1;**Y, Z, r, t, n, R⁹, R¹⁰, p, q** are defined in claim 1.

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Group VII: Claims 7-12, drawn to compounds, compositions and process of making formula**X** is oxygen;**R¹** is independently selected from halo, hydroxyl, amino, alkanoylamino, or C1-

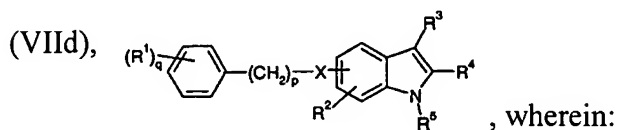
C4alkoxy, wherein the amino group is optionally substituted with an amino acid residue and the hydroxyl group is optionally esterified;

R⁵ is selected from formula (III);**R², R³, R⁴, R⁶, R⁷ and R⁸** are defined in claim 1;**Y, Z, r, t, n, R⁹, R¹⁰, p, q** are defined in claim 1.**Group VIII:** Claims 7-12, drawn to compounds, compositions and process of making formula**X** is S;**R¹** is independently selected from halo, hydroxyl, amino, alkanoylamino, or C1-

C4alkoxy, wherein the amino group is optionally substituted with an amino acid residue and the hydroxyl group is optionally esterified;

R⁵ is selected from Formula (III);**R², R³, R⁴, R⁶, R⁷ and R⁸** are defined in claim 1;**Y, Z, r, t, n, R⁹, R¹⁰, p, q** are defined in claim 1.

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Group IX: Claims 7-12, drawn to compounds, compositions and process of making formulaX is SO or SO₂;R¹ is independently selected from halo, hydroxyl, amino, alkanoylamino, or C1-

C4alkoxy, wherein the amino group is optionally substituted with an amino acid residue and the hydroxyl group is optionally esterified;

R⁵ is selected from Formula (III);R², R³, R⁴, R⁶, R⁷ and R⁸ are defined in claim 1;Y, Z, r, t, n, R⁹, R¹⁰, p, q are defined in claim 1.**Group X:** Claims 1-6, drawn to method of using the compounds of Formula (I) wherein:X is SO or SO₂;R¹ is independently selected from halo, hydroxyl, amino, alkanoylamino, or C1-

C4alkoxy, wherein the amino group is optionally substituted with an amino acid residue and the hydroxyl group is optionally esterified;

R⁵ is selected from Formula (III);R², R³, R⁴, R⁶, R⁷ and R⁸ are defined in claim 1;Y, Z, r, t, n, R⁹, R¹⁰, p, q are defined in claim 1.

The abovementioned groups are exemplary and therefore the list of groups as described is not exhaustive. Applicant is encouraged to particularly describe a compound that is not listed above by specifically pointing out the definitions of each variable.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. As stated above, this is not an exhaustive list, as it would be impossible to produce such a list under the time constraints due to the large volume of subject matter claimed in this application.

The claims herein lack unity of invention under PCT Rules 13.1 and 13.2 because, pursuant to 37 C.F.R. 1.475(a) the instant invention lacks unity of invention since under 37 CFR 1.475:

Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical feature among those inventions involving one or more of the same or corresponding special technical features...those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The structural moiety common to **Groups I-X** is the indole ring and is therefore the *technical feature*. However, this technical feature is not a *special technical feature*, because it fails to define a contribution over the prior art (see Beckers, et al. WO 01/82909 A2, for example, at p. 66) (disclosing indole compounds). Therefore, Claims 1-12 are not so linked as to form a single general inventive concept and there is a lack of unity of invention. The variables vary extensively and when taken as a whole result in vastly different compounds. Additionally, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter impose a serious burden on any examination of the claimed subject matter.

Because the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to a product, a process for the manufacture of said product, or a method of use.

Furthermore, with respect to **Groups I-X**, even if unity of invention under 37 CFR 1.475(a) is not lacking, under 37 CFR 1.475(b) a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specially designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specially designed for carrying out the said process.

Moreover, according to 37 CFR 1.475(c),

If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

In the instant case the claims are drawn to more than one product, process, and method of use. According to 37 CFR 1.475(e),

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

As a result, the claims lack unity of invention and applicant is required to elect a single invention and a single compound, including an exact definition of all substituents and variables wherein a single member at each substituent group or moiety is selected. For

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example, if a base molecule has a substituent group R1, wherein R1 is recited to be any one of H, OH, COOH, aryl, alkoxy, halogen, amino, etc., then applicant must select a single substituent of R1, for example OH or aryl and each subsequent variable position.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even if the restriction requirement is traversed (37 CFR 1.143).

Telephonic Inquiry

A telephone call was made to David Halsted, Esquire on or about December 5, 2005 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

IV. CONCLUSION

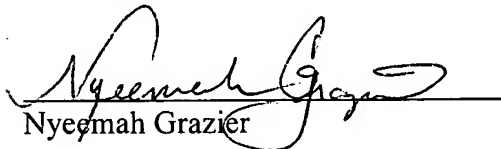
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nyeemah Grazier whose telephone number is (571) 272-8781. The examiner can normally be reached on Monday through Friday from 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272 - 0699. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

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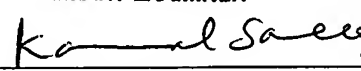
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Very truly yours,


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